REMARKS

Claims 1-12 are pending and under examination in the subject application. By this amendment, applicants have amended Claim 1 to clarify the claimed invention. Support for the amendment to claim 1 can be found throughout the application, in particular at page 8, lines 13-15. Applicants maintain no issue of new matter is raised by this amendment. Upon entry of the amendment and in view of the remarks below, applicants respectfully maintain that a Notice of Allowance is now appropriate for this application.

Rejection under 35 U.S.C. 112, First Paragraph

Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 1-12 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action states that the prior amendment to claim 1 to recite a "single liner" is allegedly not supported by the specification. In response, but without conceding the correctness of the rejection and in an earnest effort to move this application to allowance, applicants have removed the term "single liner" from the claim and replaced it with "unitary release liner". Applicants note above that the term "unitary release liner" appears, for example, in the specification at page 8, line 15. Accordingly, applicants respectfully request the reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph.

Rejections under 35 U.S.C. 103(a)

Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 1-7 and 10-12 under 35 U.S.C. 103(a) as allegedly rendered obvious by Ebert (WO 96/19205) in view of Chiang (U.S. Patent No. 4,973,468) and further in view of Min (U.S. Patent No. 5,916,587).

Certain required elements of Ebert's device are not contained in the claimed device and, more importantly, are necessarily avoided by elements claimed in the subject invention. The claimed design provides an advantage in using fewer parts than required by Ebert, in particular avoiding the adhesive overlay and the use of a peel seal disc that are central to Ebert's design. As noted throughout the specification

the adhesive layer of Ebert overlies the reservoir forming backing layer (see, e.g., page 1, lines 15-17; page 3, lines 28-29; page 5, lines 5-6; and Figures 1, 4, and 5). In contrast, the claimed device comprises an adhesive layer adhered to the backing member wherein the adhesive layer does not extend to the perimeter of the opening in said cover, but which allows a portion of the cover surrounding the perimeter of the opening to be exposed to define a cover sealing surface. Further Ebert's peel seal disc is a required cover over the agent permeable membrane and is removed as part of a subassembly with the release liner layer (see, in particular Ebert, page 6, lines 3-14). In contrast, the device of the subject invention contains a unitary release liner covering which is releasably sealed to the sealing surface of the cover by a second seal, thereby removing the need for a second membrane cover, represented by Ebert's peel seal. The Office Action notes that the claims as pending did not exclude the possibility of a device also containing Ebert's peel seal. Applicants have amended the claim 1 herein to clarify this distinction. These defined elements of the claimed device are not disclosed or suggested in Ebert and are improvements over Ebert's design. In addition to the elements as broadly claimed in claim 1, the additional elements recited in claims 4 and 5 defining a barrier layer in the liner and adhesive layers, respectively, are not disclosed nor suggested by any of the references cited by the examiner.

Moreover, neither Chiang nor Min cures these defects in Ebert. The Office Action concedes this by stating that the Chiang and Min are not relied on for their structural features but for the general teaching of the use of polymeric thickening agents and solvents or use of alkylene glycol in transdermal delivery devices. Applicants discuss the structural elements of the devices disclosed in those references to demonstrate that the combination of the references does not disclose or suggest the unique structure claimed in this application, irrespective of the drug formulation delivered by the device. Applicants maintain that the combination of Chiang and/or Min with the defective Ebert reference cannot support a rejection under 35 U.S.C. 103 for the claimed invention. Applicants restate their position that Min in fact teaches against the invention by requiring a drug containing matrix formed in part by an adhesive polymer (see, e.g., Col. 2, lines 37-38) which is contrary to the claimed invention's definition of the adhesive layer noted above, which provides for an

opening that does not contact the area where the active agent(s) passes through. The Min design provides no opening but requires the drug pass through the adhesive polymer containing matrix. Chiang similarly teaches against by requiring an adhesive be applied to a drug containing matrix (see, e.g., Col. 7, lines 4-7). Because the secondary references Min and Chiang do not cure the defects in the structural elements noted above with respect to the primary reference Ebert, but in fact teach away from Ebert (and away the claimed invention), applicants respectfully submit that the one of ordinary skill in the art would not have combined their teachings to arrive at the claimed invention. Accordingly, applicants respectfully request that rejection under 35 U.S.C. 103 be reconsidered and withdrawn.

Applicants also respectfully request the reconsideration and withdrawal of the rejection of claims 8 and 9 under 35 U.S.C. 103(a) as allegedly rendered obvious by Ebert, as applied to claims 1-7 and 10-12, further in view of Toppo (U.S. Patent No. 5,985,860).

Applicants repeat their remarks above about the defects in Ebert with respect to the claimed invention and note that Toppo does not address these defects as it does not describe any patch or drug containing reservoir technology. Again, the Office Action concedes that Topo is not relied on for teaching of the structure of a transdermal drug delivery device and, therefore, its combination with the defective Ebert reference cannot support a rejection under 35 U.S.C. 103 for the claimed invention. Applicants respectfully submit that the one of ordinary skill in the art would not have combined their teachings to arrive at the claimed invention. Accordingly, applicants respectfully request that rejection under 35 U.S.C. 103 be reconsidered and withdrawn.

Applicants also respectfully request the reconsideration and withdrawal of the rejection of claims 8 and 9 under 35 U.S.C. 103(a) as allegedly rendered obvious by Ebert, as applied to claims 1-7 and 10-12, further in view of Franke (WO 01/26637).

Applicants repeat their remarks above about the defects in Ebert and note that Franke also does not cure these defects. As with the other secondary references, the Office Action concedes that Franke is not relied on for teaching of the structure of a transdermal drug delivery device and, therefore, its combination with the defective Ebert reference cannot support a rejection under 35 U.S.C. 103. Similar to the

disclosures of Min and Chiang above, Franke describes attaching a drug containing polymer matrix layer by means of an adhesive material on the matrix alone or in combination with a "special adhesive device" which would comprise the same materials as used for the polymer matrix. See page 3 of the translated Franke application. Applicants respectfully submit that the one of ordinary skill in the art would not have combined their teachings to arrive at the claimed invention. Accordingly, applicants respectfully request that rejection under 35 U.S.C. 103 be reconsidered and withdrawn.

CONCLUSION

In view of the remarks contained herein, applicants respectfully request the reconsideration and withdrawal of the rejections and respectfully submit that a Notice of Allowance for claims 1-12 is warranted. If the undersigned can be of assistance in advancing the application to allowance, please contact the undersigned at the number set forth below.

No additional fees beyond the fee for extension of time are believed to arise due to this filing. However, if any such fees are required, the Office is hereby authorized to charge any required fees to Deposit Account No. 13-2755.

Respectfully submitted,
SCHERING-PLOUGH
HEALTHCARE PRODUCTS, INC.

Dated: **February 21, 2011**
By:
Name: **Matthew J. Golden**
Reg. No.: **35,161**
Attorney of Record
Telephone No.: (732) 594-0587

MERCK & CO. INC.
MS RY 60-30
P.O. Box 2000
126 E. Lincoln Avenue
Rahway, NJ 07065
Facsimile No.: (732) 594-4720